Exhibit F

Calculation of Damages and Penalties for the State of Montana

Declaration of Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), an economic consulting and litigation support firm located in Cambridge, Massachusetts. Since I have previously described my qualifications to this Court, I will not repeat them here.

2. I have been asked by Counsel to the State of Montana to review the Complaint in this matter;[1] to review the allegations regarding fraudulent pricing practices on the part of Defendants; and to describe the formulaic methodologies I would use to calculate both the damages to the State and its consumers if the alleged fraudulent pricing practices are proved and the penalties to the Defendants arising from those fraudulent practices.

3. The fraudulent pricing practices specifically alleged of twenty-one Defendant drug manufacturers[2] are characterized as the "AWP Inflation Scheme."[3] Through the alleged "AWP Inflation Scheme" (or "AWP Scheme"), Defendant manufacturers fraudulently increased the AWPs of selected drugs (denoted by NDCs) above the provider acquisition costs (ACs) for which the AWPs were a market signal.[4] Defendants reported the inflated AWPs to the standard national price compendia (*First DataBank (FDB), Red Book* and *Blue Book*), and the industry based reimbursement amounts on those AWPs. Since providers acquired the drugs at acquisition cost (AC) while payors (Medicare, Medicaid, private Third-Party Payers (TPPs), and consumers) paid for the drugs at reimbursement rates based on the AWPs, the increased "spreads" (AWP – AC) caused by the AWP Scheme increased the profits earned by the providers of the drugs (pharmacies, physicians) at the expense of the payors. The increased profits induced providers to move market share of the relevant drugs, the *raison d'etre* of the AWP Scheme to the drug manufacturers.[5]

---

[1] State of Montana's Second Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003 (hereafter, *Complaint*).

[2] Identified and discussed in detail in the *Complaint* in ¶¶ 214-602. I have been instructed by Counsel to exclude the GSK Group from my analysis.

[3] *Complaint*, ¶¶ 5-10.

[4] Market reliance upon reported AWPs is discussed in ¶¶ 169-172 of the *Complaint*.

[5] A more complete discussion of the fraud and its market effects are developed in ¶¶ 173-213 of the *Complaint*.

4. The relevant Plaintiffs in this matter for whom damages are alleged include, but are not limited to,[6] the following:

a) The State of Montana

- For pharmaceutical reimbursements under Medicaid (see *Complaint*, ¶¶ 15, 159-163)
- For pharmaceutical reimbursements under Medicaid for "dual eligibles" under Medicare (see *Complaint*, ¶ 158)
- For pharmaceutical reimbursements by State employees (see *Complaint*, ¶ 16)
- For pharmaceutical payments made by State agencies (see *Complaint*, ¶ 17)

b) Montana consumers

- Those consumers making drug coinsurance payments under Medicare Part B (see *Complaint*, ¶ 20)
- Those consumers making coinsurance payments under a private third-party payer plan (see *Complaint*, ¶ 20)
- Those consumers without prescription drug insurance coverage making payments out of pocket (see *Complaint*, ¶ 2).

5. The claims for damages and/or financial penalties made by Plaintiffs include, but are not limited to, the following:

a) Restitution for losses incurred by Montana residents as a result of the AWP Scheme (*Complaint*, ¶¶ 654-660);

b) Restitution of the losses suffered by the State of Montana as a result of the AWP Scheme and recovered as civil penalties for deceptive acts or practices in violation of Mont. Code Ann. §§ 30-14-103 (*Complaint*, ¶¶ 662-667);

c) Recovery of inflated Medicaid reimbursements resulting from fraudulent reporting of inflated AWPs, in violation of Mont. Code Ann. § 53-6-160(1) (*Complaint*, ¶¶ 676-678);

d) Payment of a claim for forfeiture, civil penalties, double damages and legal costs for each violation of Mont. Code Ann. § 17-8-231 under the AWP Scheme (*Complaint*, ¶¶ 681-691); and

e) Payment of punitive damages to the State of Montana (*Complaint*, ¶ 693).

6. To date, Defendants have provided incomplete data and insufficient guidance to fully interpret the data that they have provided to allow me to appropriately calculate damages for all the claims identified above. For example, insufficient data and/or insufficient data description were provided by Defendants to appropriately calculate all

[6] Since I have not had sufficient time to fully analyze all discovery materials, there may be additional Plaintiff groups and additional drugs subject to damage calculations that I will be able to address, if asked to, in a Supplementary Declaration. I anticipate that those damage calculations will make use of formulaic methods analogous to those put forward here.

damages for all injured parties alleged under the AWP Inflation Scheme. I develop methodologies for calculating damages alleged under the AWP Scheme and use them where the data permits. However, given my inability to fully analyze the data submitted by Defendants, I have been instructed by Counsel to develop alternative methodologies that allow me to calculate aggregate penalties arising from the violations alleged in the *Complaint,* in the absence of a complete production of data. I reserve the right to supplement my analyses once sufficient data become available. Given the absence of complete information to calculate all damages and penalties for all Plaintiffs injured under the AWP Inflation Scheme, the damages presented in this Declaration are conservative.

7. My Declaration proceeds as follows. In Section II, I conduct the analysis to develop the formulaic methodologies that can be used for calculating the damages and penalties induced by Defendants' conduct. In Section III, I discuss the measurement of specific components of selected formulaic methodologies and the implementation of those methodologies for those groups for which damages and penalties can be calculated. In Section IV, I implement my formulaic methodologies for those drugs, Defendants, and damage/penalty measures for which data are available. Attachment A lists additional materials relied upon and not identified in my declarations previously submitted in this matter.

II. Analysis

A. The Purpose of the Medicaid and Medicare Statutes

8. The Medicaid drug program and the federal and state initiatives to effectuate it have been designed to implement cost-based drug reimbursement. The legislation and regulation enabling the Medicaid drug program have encouraged states to base their payments on Estimated Acquisition Cost (EAC), as reflected in an early Health Care Financing Administration (HCFA) memorandum:

> "The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."[7]

As part of the process, over time states have come to require the amount allowed (AA) for Medicaid reimbursement be **the lesser of** the possible measures of cost – the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the

[7] HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: "Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." Indeed, in 1976 the Department of Health and Human Services (HHS) implemented drug reimbursement rules articulating upper limits for payments by Medicaid and other programs (45 CFR Part 19). The rules were designed to ensure that the federal government acts as a cost conscious purchaser of drugs. Of the Federal programs involved, these rules have the greatest impact on the Medicaid program. In 1983, the HHS began reviewing the department's drug reimbursement regulations. The revised regulations were published on July 31, 1987 (52 Fed. Reg. 28648).

Reimbursements$_{jk}$ for all relevant drugs and Defendant manufacturers, for the relevant Damage Period, for Medicaid and Medicare program reimbursements. The But-For Reimbursements are determined by statute.

D. Calculation of Penalties for Deceptive Practices and False Claims Under the AWP Inflation Scheme

18. Under Count II (¶¶ 662-667) of the *Complaint*, the claim is made for restitution of losses suffered by the State of Montana as a result of the AWP Scheme. Defendants conduct as alleged constitutes deceptive acts or practices in violation of Mont. Code Ann. § 30-14-103 for those transactions in which the AWP was inflated; and for which Defendant manufacturer failed to disclose material facts that the AWP exceeded the average of the wholesale price based upon a good faith and reasonable estimate; and that the Defendant manufacturer knowingly made false representations by representing that the AWP was an accurate reflection of the average wholesale price. Pursuant to Mont. Code Ann. § 30-14-142(2), the *Complaint* states that the Court can assess civil penalties of $1,000 from each defendant for each willful violation of Mont. Code Ann. § 30-14-103.

19. Under Count IV (¶¶ 682-691) of the *Complaint*, a claim for forfeiture, civil penalties, double damages and legal cost pursuant to Mont. Code Ann. § 17-8-231 is made in ¶ 691. Accordingly, it is claimed (¶ 691.C) each defendant must forfeit the entirety of their claims and pay (i) civil penalties of $2,000 per false claim, (ii) double the damages sustained by the State as a result of the false claim, and (iii) the State's legal costs incurred in connection with this action.

20. I have been directed by Counsel to assume that penalties of $3,000 can be assessed for each claim submitted for reimbursement under Medicaid and Medicare that was subject to a deceptive practice and was false.[23] The number of such claims can be calculated as follows.

21. As noted in ¶ 8 above, the allowed amount (AA) under Medicaid is to be the lesser of {the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the Usual & Customary amount (U&C) charged by a pharmacy, or the amount billed}. Likewise, as noted in ¶ 8 above, EAC is invariably the lowest price.

Hence, for any drug reimbursed under Medicaid, I have been instructed by Counsel that liability occurs as a matter of law if $AA_{jk} > EAC_{jk}$. Furthermore, as discussed above (see footnote 8), $EAC_{jk} = ASP_{jk}$ to the relevant group of providers (pharmacies, physicians). For self-administered drugs reimbursed under Medicaid, j denotes the NDC of the drug and k denotes the Defendant. For physician-administered drugs, j denotes the NDC or the J-Code and k denotes the Defendant.

22. I have been provided with information from the State sufficient to calculate AA_{jk} by claim, net of the dispensing fee. While I received from Defendants a variety of data

[23] My methodology focuses upon accurately calculating the number of complaints that were deceptive and false. Should I receive alternative direction from the Court regarding the amount of the penalty to be assessed per false and deceptive claim, the calculation of aggregate penalties will be very easy to revise to accommodate those alternative directions. The revised calculation is simple arithmetic.

sets summarizing (to varying degrees of completeness) invoice information, rebates information and other accounting information, I have not received from Defendants sufficient explanation and clarification of these data to accurately calculate the ASP_{jk} by NDC and/or J-Code for most drugs and most Defendants in this matter. Indeed, the data that I have been able to use to analyze liability using ASPs have been developed as part of the MDL AWP litigation addressing the Track 1 Defendants and the Connecticut AWP litigation.

Given this limited ability to make use of discovery materials, I have developed a method to make use of the existing information to draw conclusions regarding liability. Specifically,

a) For claims for reimbursement for single-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC, EAC will be the lesser of the alternative reimbursement bases.[24]
- AWP – (16.6%-20%)[25] = WAC
- I understand that the retail acquisition costs (RAC) is approximately equal to WAC and indeed may be slightly less {that is, RAC (EAC) < WAC}, perhaps 1-2% of AWP.[26] To be conservative, I assume that RAC = EAC ≈ WAC.[27]
- Using the upper bound of these discounts off AWP, if AA > AWP – 20%, AA exceeds EAC.
- Using the lower bound of these discounts off AWP, AA > AWP – 16.6%, AA exceeds EAC.
- Absent a measure of ASP, I let the threshold for liability be AA > AWP – 20%. For sensitivity analysis, I let the threshold for liability be AA > AWP – 16.6%. In each case, if AA exceeds the threshold I conclude AA fraudulently exceeds EAC.

b) For claims for reimbursement for multi-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC; since FUL > EAC; and since Montana does not have a state MAC; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that EACs (i.e., ASPs or RACs) < AWP – (16.6%-66%)[28] over the period 1991-2002.

---

[24] The U&C is the "walk-in" price paid by uninsured cash payers; it is usually ≈ AWP.

[25] These discounts off AWP are equivalent to spreads of 20%-25% above WAC. For example, if AWP – 20% = WAC; then AWP (100%-20%) = .80*AWP = WAC; and AWP = 1.25 WAC or WAC + 25%.

[26] See footnote 9 above.

[27] This understanding is corroborated by Defendants' Experts; see footnote 8 above.